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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,587	09/11/2000	Klaus Abraham-Fuchs	P00.1120	1296
7590 04/19/2005 Schiff Hardin & Waite 6600 Sears Tower Chicago, IL 60606			EXAMINER PATEL, NIHIR B	
			ART UNIT 3743	PAPER NUMBER
DATE MAILED: 04/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/581,587	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner Nihir Patel	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on September 11<sup>th</sup>, 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06.15.2000</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No 09/581587 filed on September 11<sup>th</sup>, 2000.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims **19, 25, 28, 29 and 36** are rejected under 35 U.S.C. 102(e) as being anticipated by Coutre et al (US 5,643,212).

Referring to **claim 19**, Coutre discloses an infusion pump management system for suggesting an adapted course of therapy that comprises a sensor **608 (see figure 37 and column 14 lines 35-37)** for emitting real-times values representing a physiological parameter of a patient;

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a control unit **610** (see **figure 37 and column 14 lines 20-23**) supplied with the real-times values (see **column 14 lines 44-46**); a fluid administration device selected from the group consisting of infusion devices and perfusion devices **402** (see **figure 30 and column 9 lines 16-20**), in communication with the control unit **610**, the fluid administration device containing a solution to be administered (see **column 9 lines 16-20**); the control unit **610** controlling the fluid administration device to dispense the solution dependent on the real-time values (see **column 14 lines 45-60**); and the control unit **610** comprising an expert system which processes the real-times values as the real times values are received from the sensor, to obtain a processes result, and the control unit continually updating of the fluid administration device dependent on the processed result (see **column 14 lines 45-60 and column 15 lines 1-15**).

Referring to **claim 25**, Coutre discloses an apparatus wherein the control unit **610**, based on the processed results, automatically controls the fluid administration device to change dispensing of the solution to adjust for a deficient supply, a balanced supply and an excess supply of the solution (see **column 14 lines 45-60**).

Referring to **claim 28**, Coutre discloses an apparatus that further comprises an alarm connected to the control unit, the alarm being triggered by the control unit dependent on at least one of the real-time values (see **column 12 lines 45-60**).

Referring to **claim 29**, Coutre discloses an apparatus wherein the sensor **608** is a sensor from the group consisting of glucose sensors (see **column 14 lines 35-40**) and potassium sensors, and wherein the control unit **610** controls the fluid administration device to administer a fluid for influencing a metabolism selected from the group consisting of glucose metabolism and potassium metabolism.

Referring to **claim 36**, Coutre discloses an apparatus wherein the sensor **608** is a sensor selected from the group consisting of a sensor for measuring temperature of the patient (see **column 14 lines 35-44**).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coutre et al. (US 5,643,212).

Referring to **claim 20**, the applicant claims a fluid administration device that comprises plurality of different solutions to be administered in respectively different dispensed amounts, and wherein the control unit controls administration of the different solutions in the different dispensed amounts dependent on the processing result. Coutre discloses plurality of solutions that are to be infused on additional lines (see **column 9 lines 25-40**). Therefore it is obvious to one in the ordinary skill of the art that the plurality of different solutions as taught by Coutre be administered in respectively different dispensed amount in order to provide the correct amount of the required solution to the patient.

Claims **21 through 24 and 32 through 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Coutre et al. (US 5,643,212) in view of Uber, III et al. (US 5,840,026).

Referring to **claims 21 through 24 and 32 through 35**, Coutre discloses the applicant's invention as claimed with the exception of providing a mixing device connected to all of the

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different solutions wherein the mixing device has a single outlet at which all of the different solutions are dispensed in the dispensed amount, controlled by either manually or control unit to a patient. Uber discloses a patient specific dosing contrast delivery systems and methods that does provide a mixing device **71 (see figure 3a)** connected to all of the different solutions wherein the mixing device has a single outlet at which all of the different solutions are dispensed in the dispensed amount, controlled by either manually or control unit to a patient. Therefore it would have been obvious to modify Coutre's invention by providing a mixing device connected to all of the different solutions wherein the mixing device has a single outlet at which all of the different solutions are dispensed in the dispensed amount, controlled by either manually or control unit to a patient as taught by Uber in order to mix and deliver the correct amount of solution to the patient.

Claims **26 and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Coutre et al. (US 5,643,212) in view of Pfeiffer et al. (US 5,902,253).

Referring to **claims 26**, Coutre discloses the applicant's invention as claimed with the exception of providing a source of calibrating solution and rinsing and calibrating means connected to the sensor for rinsing the sensor and for calibrating the sensor with the calibrating solution. Pfeiffer discloses an apparatus for analyzing body fluids that does provide a source of calibrating solution and rinsing and calibrating means connected to the sensor for rinsing the sensor and for calibrating the sensor with the calibrating solution. Therefore it would have been obvious to modify Coutre's invention by providing a source of calibrating solution and rinsing and calibrating means connected to the sensor for rinsing the sensor and for calibrating the sensor with the calibrating solution as taught by Pfeiffer in order to obtain accurate results.

Referring to **claim 27**, Coutre discloses the applicant's invention as claimed with the exception of providing rinsing and calibrating means that is connected to and controlled by the control unit. Pfeiffer discloses an apparatus for analyzing body fluids that does provide rinsing and calibrating means that is connected to and controlled by the control unit. Therefore it would have been obvious to modify Coutre's invention by providing rinsing and calibrating means that is connected to and controlled by the control unit as taught by Pfeiffer in order to have the sensor in operating conditions at all times.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coutre et al. (US 5,643,212) in view of Thornton (US 5,263,491).

Referring to **claim 30**, Coutre discloses the applicant's invention as claimed with the exception of providing a sensor for sensing a parameter related to caloric metabolism. Thornton discloses an ambulatory metabolic monitor that does provide a sensor for sensing a parameter related to caloric metabolism. Therefore it would have been obvious to modify Coutre's invention by providing a sensor for sensing a parameter related to caloric metabolism as taught by Thornton in order to determine the quantity of solution to be given to the patient.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coutre et al. (US 5,643,212) in view of Chen et al. (US 5,670,057).

Referring to **claim 31**, Coutre discloses the applicant's invention as claimed with the exception of providing a sensor selected from the group consisting of fluid sensors and electrolyte sensors, and wherein the control unit controls the fluid administration device to administer a fluid for influencing a metabolism selected from the group consisting of fluid metabolism and electrolyte metabolism. Chen discloses an apparatus and method for

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automatically performing peritoneal equilibration tests that does provide a sensor selected from the group consisting of fluid sensors and electrolyte sensors, and wherein the control unit controls the fluid administration device to administer a fluid for influencing a metabolism selected from the group consisting of fluid metabolism and electrolyte metabolism. Therefore it would have been obvious to modify Coutre's invention by providing a sensor selected from the group consisting of fluid sensors and electrolyte sensors, and wherein the control unit controls the fluid administration device to administer a fluid for influencing a metabolism selected from the group consisting of fluid metabolism and electrolyte metabolism as taught by Chen in order to obtain accurate information.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (571) 272 4791.

NP  
April 14<sup>th</sup>, 2005

  
Henry Bennett  
Supervisor Patent Examiner  
Group 2700